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7952 - Plaintiffs' Response in Opposition to Defendants' Motion for Summary Judgment as to Plaintiffs Lisa and Mark Hyde's Claims - Filed Redacted

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Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark Stephen O'Connor (AZ Bar No. 011029)
mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co-Lead/Liaison Counsel for Plaintiffs

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFFS LISA AND MARK HYDE'S CLAIMS** **(**Assigned to the Honorable David G. Campbell)

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND SUMMARY OF ARGUMENT

On [redacted] a Bard G2®X filter was implanted in Plaintiff Lisa Hyde.[1] The

[1] As noted in Bard's motion, Plaintiffs and Defendant disagree as to which Bard IVC filter model Ms. Hyde was implanted with. Plaintiffs assert that, more likely than not, the filter at issue here is a G2X and provide ample evidence supporting this contention.

filter was defective and as such, after placement the filter [redacted]

Bard moved for partial summary judgment under Federal Rule of Civil Procedure 56. The motion was also brought under Wisconsin substantive law on the following counts alleged by Plaintiffs: Strict liability design defect (Count III); Strict liability failure-to-warn (Count II); Negligent failure-to-warn (Count VII); Breach of implied warranty (Count XI); Negligent ad fraudulent misrepresentation/concealment (Counts VIII, XII, XIII) and claim for Violation of Wisconsin Law (Count XIV); and Failure to recall/retrofit (Count VI).[2]

Plaintiffs oppose Bard's motion. Plaintiffs have provided abundant evidence supporting each of their claims in this action and, consequently, there exist genuine disputes to multiple material facts and summary judgment is inappropriate.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The movant also "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Disputed facts that might "affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be 'such that a reasonable jury could return a verdict for the nonmoving party.'"

[SOF ¶¶ 150, 153, 162, 163]. Regardless, Bard notes that the filter type has no bearing on its Motion for Summary Judgment. [Def's. Mot. for Summ. J. n.2]. It is worth noting that the Eclipse filter did nothing to address the design defects of the G2 and G2X, so the difference between the models is unimportant. [SOF ¶ 102.]

[2] Plaintiffs do not oppose Bard's motion as to the count for Breach of implied warranty (Count XI) and Failure to recall/retrofit (Count VI), but reserve the right to keep these factual claims under other existing causes of action.

Placencia v. I-Flow, 2012 WL 5877624 (D. Ariz. 2012)(quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The Court must "draw[] from the underlying facts" any permissible inference "in the light most favorable to the nonmoving party." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88, 106 S. Ct. 1348, 89 L. ED. 2d 538 (1986).

III. ARGUMENT AND CITATION OF AUTHORITY

A. Choice of Law

The parties have stipulated and agreed that Wisconsin choice-of-law rules apply to this case. Under Wisconsin's choice-of-law rules, Nevada substantive law should ultimately apply to the *Hyde* case.

Factually, Ms. Hyde had her filter implanted in Wisconsin. [SOF ¶ 151]. Shortly thereafter, Ms. Hyde moved to Nevada. [SOF ¶ 156]. Ms. Hyde has continued to live in Nevada. [SOF ¶ 7]. She [redacted] in Nevada. [SOF ¶¶ 156-60]. The [redacted] was conducted in California. [SOF ¶ 161]. Most importantly, Nevada is where the filter malfunctioned and caused injury to Ms. Hyde. [SOF ¶ 156]. Under Wisconsin's choice-of-law rules, these facts indicate that Nevada law should apply to *Hyde*.

In Wisconsin before 2012, cases applied two similar choice-of-law methods: the grouping-of-contacts analysis and the choice-influencing-factor analysis. In *NCR Corp. v. Transport Ins. Co.*, 344 Wis.2d 494 (2012), the Wisconsin Court of Appeals reconciled these two methods. The court explained that "the grouping-of-contacts analysis is subsumed by the choice-influencing-factors analysis. Specifically, the grouping-of-contacts analysis is merely step one of the choice-influencing-factors analysis." *NCR Corp*., 344 Wis. 2d 494 at ¶ 11.

The choice-influencing-factor analysis consists of two steps. First, the Court must "judge whether the contacts of one state to the facts of the case are so obviously limited and minimal that application of that state's law constitutes officious intermeddling." *Beloit Liquidating Trust v. Jeffrey T. Grade, et al.*, 270 Wis. 2d 356, ¶ 24 (2004)

(quotation mark omitted). There is a ***weak*** presumption in favor of applying the forum law. *NCR Corp*., 344 Wis. 2d at ¶ 12.

The grouping-of-contacts analysis is nearly identical to the first step of the choice-influencing-factor analysis. Courts should consider: (a) the place of contracting; (b) the place of negotiation of the contract; (c) the place of performance; (d) the location of the subject matter of the contract; and (e) the domicile, residence, nationality, place of incorporation and place of business of the parties. *Haines v. Mid–Century Ins. Co.*, 47 Wis. 2d 442, 446, 177 N.W. 2d 328 (1970) (citing RESTATEMENT (SECOND) OF CONFLICTS § 188 (Proposed Official Draft, Part II)). **Where tort law is implicated, we additionally consider the locations of the injurious conduct and injury.** *NCR Corp*., 344 Wis. 2d 344 at ¶ 13 (citing to *Drinkwater v. American Family Mutual Insurance Co.*, 290 Wis.2d 642, ¶ 44 (2006)) (emphasis added.); *Beloit Liquidating*, 270 Wis.2d at ¶ 24; see also RESTATEMENT (SECOND) OF CONFLICTS § 145 (1971). If one state's contacts are clearly more significant, the Court may terminate the analysis and apply that state's law. *Drinkwater*, 290 Wis.2d 642, ¶ 40.

Here, the place of contracting, the place of negotiation, and the location of the subject matter of the contract carry no weight in choosing Wisconsin or Nevada law. There is no contract at issue here and Ms. Hyde did not purchase the filter herself. In *NCR Corp.*, the Court reached similar conclusions based on NCR Corp not being a party to the contract at issue. *See NCR Corp.*, 344 Wis. 2d 344 at ¶¶16-19. Without a contract to analyze, the place of performance factor also fails to favor Wisconsin or Nevada law. It could be said that as the location of implantation, Wisconsin is the place of "performance." However, this factor seems to indicate the presence of a contract, of which there is none between Ms. Hyde and Bard. Ms. Hyde did not have a contract nor was she party to a contract to purchase her filter directly from Bard. In fact, billing records indicate that Ms. Hyde bought the filter from [redacted] the hospital where she received the filter. [SOF ¶ 150] As such, these four factors fail to point conclusively to Nevada or Wisconsin as the proper forum.

That leaves the fifth factor, domicile and residence. Currently and at the time of injury, Ms. Hyde was domiciled in the state of Nevada. Bard, on the other hand, conducts business equally among all 50 states. As such, this fifth fact points toward Nevada as the more significant forum.

Since tort law is implicated in the *Hyde* case, the Court should consider and give great weight to the location of injurious conduct and injury. Here, the filter malfunction, injury, and treatment occurred in Nevada. Historically, Wisconsin Courts have consistently held the location of injury to be the most important factor in weighing state contacts. *See, e.g., NCR Corp.*, 344 Wis. 2d at ¶ 21 (holding that injurious conduct and injury are "qualitatively stronger than any of the other[]" factors); *See generally*, *Drinkwater*, 290 Wis.2d 642 (ultimately holding that Wisconsin law applied as the injury and accident occurred in Wisconsin, among other reasons); *See also*, *Johnson v. Mylan Inc.*, 107 F.Supp. 3d 967, 970 (E.D. Wis. 2015) (applying the grouping-of-contacts analysis and finding the case had the most significant relationship with Wisconsin, as the illness, treatment, and death occurred there and thus, Wisconsin substantive law should apply).

Nationally, when conducting a choice-of-law analysis and comparing the significance of contacts between states, Courts have repeatedly held there is a presumption in favor of using the laws of the state in which the injury occurred, including for products liability actions.[3]

Though Ms. Hyde's filter was implanted in Wisconsin, Nevada is the current domicile of Ms. Hyde and most importantly, the location of the filter malfunction, injury,

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[3] *See, e.g., Peoples Bank and Trust Co. v. Piper Aircraft Corp.*, 598 F. Supp. 377 (S.D. Fla. 1984) (applying Florida choice-of-law rules); *Millar-Mintz v. Abbott Laboratories*, 268 Ill. App. 3d 566, 206 Ill. Dec. 273, 645 N.E.2d 278 (1st Dist. 1994); *Beasock v. Dioguardi Enterprises, Inc.*, 100 A.D.2d 50, 472 N.Y.S.2d 798 (4th Dep't 1984); *Morgan v. Biro Mfg. Co., Inc.*, 15 Ohio St. 3d 339, 474 N.E.2d 286 (1984); *Byers v. Lincoln Elec. Co.*, 607 F. Supp. 2d 840 (N.D. Ohio 2009) (Ohio choice-of-law rules*); Ruiz v. Weiler & Co., Inc.*, 860 F. Supp. 602 (N.D. Ill. 1994), aff'd, 89 F.3d 320, Prod. Liab. Rep. (CCH) ¶ 14668, 35 Fed. R. Serv. 3d 1053 (7th Cir. 1996).

and subsequent treatment. Given these facts, the first step of the choice-influencing-factors analysis and the grouping-of-contacts analysis overwhelmingly favors the application of Nevada substantive law to the *Hyde* case.

As the place of injury and current domicile, Nevada has such significant contacts and Wisconsin's contacts are "so obviously limited and minimal that application of that state's law constitutes officious intermeddling," there is no need to proceed to the second step of the choice-influencing-factor analysis. Courts should proceed to the factors only after concluding that the grouping-of-contacts analysis did not produce a clear favorite. *See NCR Corp.*, 344 Wis. 2d 344 at ¶¶ 22-23 (holding that Ohio's respective contacts are so obviously limited and minimal…that the court need not proceed to step two); *see also, Heath v. Zellmer*, 35 Wis. 2d 578, 595 (1967); *Drinkwater*, 290 Wis. 2d 642 at ¶ 40.

However, assuming *arguendo*, that the Court does proceed to the second step of the choice-influencing-factors analysis, it would be further confirmed that Nevada substantive law should apply to *Hyde*. This second prong involves weighing the following five factors: (1) predictability of results; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forums governmental interests; and (5) application of the better rule of law. *NCR Corp.*, 344 Wis. 2d 494 at ¶ 14.

The first factor favors neither Wisconsin nor Nevada. As the court in *Beloit* explained, this factor looks into where the parties predominantly conducted business. Here, Bard operates in all 50 states, without favor to Wisconsin or Nevada. Ms. Hyde, as an individual, seemingly does not "conduct" business anywhere. Thus, the first factor fails to give weight to Nevada or Wisconsin.

Maintenance of interstate order, the second factor, would be accomplished by application of Nevada law. In *Heath v. Zellmer,* 35 Wis. 2d 578 (1967), the Wisconsin court explained that "deference to the substantial interests of another state are necessary and for a state that is only minimally concerned with a transaction or tort to thrust its law upon the parties would be disruptive of the comity between states." *Heath*, 35 Wis. 26 at

596. Ms. Hyde is currently a resident of Nevada. Nevada has a strong interest in applying its own state law to a case where one of its residents was injured in Nevada and continues to reside in Nevada. It makes little sense to "thrust" Wisconsin law when Ms. Hyde has not lived there for over 5 years and had no injuries as a result of her filter when she did reside there.

The third factor indicates a preference for a "simple and easily applied rule of substantive or procedural law." *Beloit Liquidating Trust*, 270 Wis. 2d 356 at ¶ 28. Typically, this factor favors applying the law of the state where the deciding court sits. However, this analysis is not possible here as we have an Arizona Court deciding between Wisconsin and Nevada law. However, it is worth noting that Nevada and Arizona are both within the Ninth Circuit's jurisdiction. As such, this factor slightly favors applying Nevada law.

The fourth factor heavily weighs in favor of Nevada. With respect to Bard itself, Nevada and Wisconsin have equal interest in regulating a corporation that marketed, sold, and distributed a defective product within their borders. However, Nevada has an extremely strong governmental interest in protecting a resident who was injured in state.

The fifth and final factor favors Nevada as well. The fifth factor requires courts to "select the law[s] that most adequately do[] justice to the parties and have the greatest likelihood of being applicable with justness in the future." *Beloit Liquidating Trust*, 270 Wis. 2d 356 at ¶ 31 citing to *Heath*, 35 Wis. 2d at 598. As previously stated, justice would indicate applying the law of the state where Ms. Hyde currently resides and was injured.

In sum, the first step of Wisconsin's choice-of-law rule heavily favors Nevada law applying to *Hyde*. The analysis can and should stop there, as Wisconsin's contacts are so minimal that it would be unreasonable to apply Wisconsin law to this case. However, if the Court continues on to the second step, Nevada continues to be favored. One cannot ignore the overwhelming weight that should be given to Nevada as the current residence

and domicile of Ms. Hyde and as the location of filter malfunction, injury, and treatment. As such, this Court should choose Nevada substantive law to apply to the *Hyde* case.[4]

B. There Is Sufficient Evidence To Support Plaintiffs' Claim for Strict Liability Failure to Warn (Count II)

Wisconsin Statute § 895.047 governs all strict products liability claims in Wisconsin. For failure to warn cases, the statute states that "[a] product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). A plaintiff must also prove that the defective condition rendered the product unreasonably dangerous, that the defective condition existed at the time the product left the control of the manufacturer, that the product reached the user or consumer without substantial change in the condition in which it was sold, and that the defective condition caused the claimant's damages. Wis. Stat. § 895.047(1)(b–e).

The statute provides two defenses on which Bard bases its motion for summary judgment against Plaintiffs' strict liability failure to warn claims: (1) the **rebuttable** presumption that the product is not defective (also known as the "government rules defense") and (2) that a court should dismiss an action if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product. Bard also argues that Plaintiffs' strict liability failure-to-warn claim fails because Plaintiffs have not proffered an alternative warning that would have made the Bard filter "safe."

i. <u>The Rebuttable Presumption ("Government Rules Defense")</u>

[4] Although Nevada substantive law should be applied to this case, Bard only moved for judgment under Wisconsin law, so Plaintiffs respond by applying Wisconsin law. However, Plaintiffs' claims also survive under Nevada law.

With regard to the government rules defense, cases applying Wisconsin law have found that the when assessing the application of a government standards rebuttal, "parties **may not present evidence regarding the 510(k) clearance process** or subsequent FDA enforcement actions" because "[t]he 510(k) process is not a safety statute or administrative regulation." *Williams v. Boston Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D.W. Va. Apr. 12, 2016) (applying Wisconsin law), citing to *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755-56 (S.D. W. Va. 2014)(emphasis added); *See also Hall v. Boston Scientific Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D. W. Va. Feb. 27, 2015) (applying Wisconsin law) ("As an initial matter, 510(k) is not a 'relevant standard' here. Section 895.047 concerns whether a defect rendered the product 'unreasonably dangerous,' § 895-.047(1), and, as the [US] Supreme Court has held[5], 510(k) compliance does not go to the safety of a product.")

As such, Bard should not be awarded the presumption of the Wisconsin government rules defense when its devices were never approved via a safety and effectiveness process, standard, condition, or specifications adopted or approved by a federal or state law or agency. [See also, Plaintiffs' Response in Opposition to Defendants Motion for Summary Judgment Regarding Preemption, Docket #7369].

Moreover, even if the Court were to find that the presumption applies, Plaintiffs have presented ample rebuttal evidence to rebut the presumption and show that the G2/G2X filter did in fact have design defects, as proferred, *infra*, in Section C and had a defective, wholly inadequate warning, as argued, *infra*, in Section D(1).

[5] The 510(k) process is not a safety statute or administrative regulation. The Supreme Court has determined that "the 510(k) process is focused on equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996); *See also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) ("While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence.") (internal quotation omitted).

ii. Damages Caused by Known, Inherent Characteristics of the Product Defense

Bard also argues that Wisconsin law shields it from liability as the damage was caused by a known and inherent characteristic of the product and that Plaintiffs have not offered any evidence of an alternative warning. While generally, IVC filters and all medical devices do have adverse events, Bard's G2/G2X filter experienced events at a much higher rate than Bard's Simon Nitinol® ("SNF") or Recovery® and other competitive filters, and those increased risks were admittedly due to design issues (See Section C, *infra*).

Bard's own internal complaint tracking data indicates that from market release through July 2010, the G2 Filter had a reported migration failure rate of 0.121% (1.21 out of every 1000) of all devices sold, and applying the "consensus" of 95-99% of similar events not reported, the actual rate could have been as high as 121 out of every 1000 (12.1%). This figure was approximately fifteen times greater than the average for all competitor devices of .008% (or .8% if applying the consensus non-reported events rate). [SOF ¶ 89]. Bard's own internal complaint tracking data indicates that from market release through July 2010, the G2/G2X had a reported perforation failure rate of 0.132% (1.3 out of every 1000), and applying the "consensus" of 95-99% of similar events not reported, the actual rate could have been as high as 130 out of every 1000 (13%) . [SOF ¶ 89]. With regard to migration, internal complaint data indicates that from market release through July 2010, the G2 Filter had a reported migration failure rate of 0.121% (1.21 out of every 1000) of all devices sold, and applying the "consensus" of 95-99% of similar events not reported, the actual rate could have been as high as 121 out of every 1000 (12.1%). [SOF ¶ 89].

In contrast, Bard found that the reported perforation and migration failure rates for all competitor devices during the same time period was 0.013% (1.3 out of every 10,000) and 0.008% (8 out of every 100,000) of devices sold, and applying the "consensus" of 95-99% of similar events not reported, the actual rate could have been as high as 13 and

0.8 out of every 1000 (1.3%), respectively. [SOF ¶ 89]. Accordingly the G2 filter, based on this clinical data posed an increased risk 10 times (perforation) and 15 times (migration) greater than all competitor devices.

John McDermott, President of Bard Peripheral Vascular from 1999-2008, closely monitored the reporting rates of complications of Recovery and G2 to the predicate SNF and competitive filters on a monthly basis. [SOF ¶ 125].

Given this increased risk presented specifically by the G2 family of devices, it simply cannot be said that Ms. Hyde was injured by known and inherent characteristic of the product.

C. There Is Sufficient Evidence to Support Plaintiffs' Strict Liability Design Defect Claim (Count III)

Wisconsin's statute for product liability claims holds a manufacturer strictly liable for design defect where (1) the product contains a design defect; (2) the defective condition rendered the product "unreasonably dangerous"; (3) the defective condition existed at the time the product left the manufacturer's control; (4) the product reached the user without substantial changes[6]; and (5) the defective condition caused the plaintiff's damages. Wis. Stat. § 895.047(1). As stated above, evidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency creates a rebuttable presumption that the product is not defective.[7] *Id.*

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[6] The reasonable inference from the records in this case is that the filter implanted in Ms. Hyde did not undergo any changes from the time it left the manufacturer to the time of implantation. Ms. Hyde's implantation [redacted] [SOF ¶ 152]. [redacted], having used Bard IVC filters for "a long time" ostensibly would recognize any substantial change to the filter he was implanting and would note same. [redacted] Dep. Tr. at 18:8-9]. Since all reasonable inferences are to be drawn in a light most favorable to Plaintiffs in this case, it stands that the evidence supports this prong of Wisconsin's defective design law. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

[7] As argued, *supra*, the rebuttable presumption should not apply to this case because the 510 (k) clearance process is not a safety statute or administrative regulation. In the

Wisconsin Statute § 903.01 provides the following guidance for ascertaining how the rebuttable presumption operates:

> Except as provided by statute, a presumption recognized at common law, or created by statute, including statutory provisions that certain basic facts are prima facie evidence of other facts, imposes on the party relying on the presumption the burden of proving the basic facts, but once the basic facts are found to exist the presumption imposes on the party against whom it is directed the burden of proving that the nonexistence of the presumed fact is more probable than its existence. § 903.01

In applying this, the Court can grant summary judgment based on the presumption of non-defectiveness if (1) Bard establishes the "basic facts" triggering the presumption, namely that Bard complied with relevant standards, conditions, or specifications; and (2) Plaintiffs fail to provide sufficient evidence to create a genuine issue of material fact as to whether the non-existence of the presumption is more probable than its existence. *Hall v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 23975 (S.D. W.V. 2015) (applying Wisconsin substantive law).

Plaintiffs have provided the requisite evidence to create a genuine issue of material fact on whether Wisconsin's presumption of non-defectiveness exists in this case. Specifically, Plaintiffs have listed several alleged defects of the G2/G2X filter at issue and have reinforced the allegations with an abundance of expert testimony, Bard documents and even testimony from Bard's own corporate witnesses.

First, Plaintiffs' engineering expert, Robert McMeeking, Ph.D. ("Dr. McMeeking"), offered testimonial evidence of the defective design of the G2/G2X filters, thereby creating a genuine issue of material fact. Dr. McMeeking testified that Bard failed to design the G2/G2X filters in a way that reduced the risks of tilting, perforation, migration and fracture by fatigue to the filter. [SOF ¶ 18]. Specifically, Dr. McMeeking offers testimony that Bard's choice to design the G2/G2X without caudal anchors or

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interest of efficiency, Plaintiffs incorporate the arguments from the preceding section to Section C.

other features that would minimize and/or prevent caudal migration constitutes a design defect that leads to tilt and perforation. [SOF ¶¶ 168-69]. Further, Plaintiffs' expert testified that there were a number of design choices that Bard should have considered such as using tubing material, using different arm dimensions/diameters and including a different number of arms altogether. [SOF ¶ 170]. Bard could have developed penetration limiters sooner than it ultimately did and could have redesigned the filter configuration to try and find "a better combination of phenomena that would improve the behavior of the filter in terms of the risks involved." [SOF ¶ 168]. Dr. McMeeking also provides opinions regarding the inadequate testing done to identify worst-case scenario performance of the G2/G2X filters in assessing the performance of the design and consequences of the design. [SOF ¶ 171]. According to Plaintiffs' expert testimony, "**it's the design itself that is the cause of the dangerous failures**" that took place in Ms. Hyde's case. [SOF ¶ 172].

Additionally, Bard's own data provides sufficient evidence to support a claim of design defect in this case. Bard's internal data regarding the G2 filter showed that it had stability problems with respect to tilt and caudal migration. [SOF ¶ 79]. Internal company documents reveal that Bard itself was concerned that there were design problems. [SOF ¶ 81]. Plaintiffs have evidence that as early as 2006 Bard acknowledged a need to redesign the G2 filter to deal with caudal migration and tilt. [SOF ¶¶ 81, 87]. According to Bard's own internal analysis, its G2 device, as designed, presented an "unacceptable risk." [SOF,¶ 87]. Bard's Quality Engineering Manager, Natalie Wong, also offered testimony supporting the design defect allegations pertaining to the G2/G2X. She testified, for example, that Bard's G2 line of filters had undesirable caudal migration resistance. [SOF ¶ 79]. Kris Kandarpa, M.D., the Medical Monitor of the EVEREST clinical trial study for Bard filters also expressed his concern about the design defects of the G2 filter family, stating that Bard should "consider a redesign" based on the number of adverse events and serious adverse events of the filters. [SOF ¶ 91].

Every iteration of Bard's IVC filters was an attempt to cure the design defects of the previous filter, with the exception of the Recovery filter. The G2 filter was designed in response to safety reports Bard received concerning the Recovery filter, including deaths and filter migrations. [SOF ¶ 63]. Bard originally intended for its SNF to be the stated predicate device for the G2 filter, but the G2 filter failed migration resistance testing when compared to the SNF. [SOF ¶ 315]. Consequently, Bard used the Recovery filter as the predicate device for its G2 filter. [SOF ¶ 65]. The G2 filter failed to improve upon the design failures of the Recovery filter, as intended.

As aforementioned, even the testimony of Bard's own corporate officers provides evidence supporting Plaintiffs' design defect claim. For example, Christopher Ganser admitted that there were design defects in the G2/GX. During his deposition, Mr. Ganser provided the following testimony:

> Q. There were some defects in the design of the G2 that was leading to the problems described in Dr. Civarella's February 2006 HHE; don't you agree sir?
>
> A. **There were issues with the design that needed to be addressed**.
>
> [SOF ¶ 173].

Rob Carr, Bard's Product Manager, who was involved with the development of the first Bardat both NMT (pre Bard acquisition, and then at BPV retrievable filter, also provided testimonial evidence supporting Plaintiffs' design defect claims:

> Q. But my question was a little more specific than that. It relates to those patients that were implanted with a filter, the filter was centrally placed in the vena cava.
>
> A. Yes.
>
> Q. Was there clinical data indicating that the G2 and the G2 Express were subsequently tilting after placement?
>
> A. Yes. [SOF ¶ 174].
>
> ***
>
> Q. So the thought was by changing the anchor system Bard could prevent the filter from tilting, if there's a cough by the patient, if there's a Valsalva

maneuver, if the patient has changes in blood volume, if there is clot that forms at or around the filter. Am I correct?

A. Reduce the number.

Q. All right. So Bard was of the view that if we change the anchoring system, these known or these thought-to-be causes for tilt would be reduced?

A. Yes. [SOF ¶ 175].

Mr. Carr's testimony regarding the G2/G2X filters' propensity to tilt after being perfectly centrally placed in the vena cava and the company's endeavors to make changes to the filter to make it better and safer certainly provides enough evidence for a trier of fact to determine whether or not there was a design defect. Plaintiffs have ample evidence to create a genuine issue of material fact on whether Wisconsin's presumption of non-defectiveness exists in this case.

Defendants argue that Plaintiffs have not presented evidence of a reasonable alternative design and so a design defect contention is not permitted under Wisconsin law; this argument is meritless, as there is ample evidence of a reasonable alternative design. The predicate device, the SNF, is the prime example of a reasonable alternative design. Early clinical studies demonstrated that migration of the SNF device was rare (2 of 258, or 0.8%) concerning patients who received filters between February 1988 and November 1990. [SOF ¶ 5]. During a migration resistance test conducted by Bard in March 2004 it was discovered that the SNF had a higher resistance to migration than the Recovery filter and competitive filters. [SOF ¶ 34-35]. By 2005 Bard's own sales force discussed internally that the SNF was the "safest filter on the market." [SOF ¶ 61]. Bard originally intended the predicate device for the G2 filter to be the SNF, but the G2 filter failed migration resistance testing when compared to the SNF. [SOF ¶¶ 78-80, 315].

Plaintiffs also have evidence that by November 2005, Bard was aware of the fact that the G2 filter had a perforation rate that was approximately 10 times that of the SNF. [SOF ¶¶ 77-78]. Again, Bard's own Corporate Clinical Affairs Director, Dr. Ciavarella questioned why Bard was even selling the G2 Filter that had been approved when the SNF "has virtually no complaints associated with it." [SOF ¶ 80]. Moreover, Dr.

McMeeking, Plaintiffs' engineering expert, testified that the SNF is a safer and better filter than the other Bard filters. [SOF ¶¶ 176-77].

Defendant argues in its motion that the SNF device cannot be the reasonable alternative design because the filter cannot be retrieved, but this argument fails. That the SNF was a permanent filter does not make it less of a reasonable alternative design for the G2/G2X filter because the G2/G2X filter, as all Bard IVC filters, was submitted for clearance by the FDA as a *permanent* device. [SOF ¶ 71]. The Recovery filter, like the SNF, is a permanent device. Defendant cannot have its cake and eat it, too, by purporting to the FDA that the predicate devices are *identical* and then arguing to the Court that the predicate devices are too *different* from the G2 due to the issue of permanence versus optional retrievability. Moreover, the Patient Brochure for the G2 device itself states, "G2 Filter System **for Permanent Placement**." [SOF ¶ 178]. Finally, testimony from Bard's Product Manager, Rob Carr again provides evidence of the G2 and G2X filters being permanent devices just as the SNF:

> Q. And during this time frame – that is the Recovery era, the G2 era and the G2 Express era – did Bard have a truly permanent filter that was commercially available?
>
> A. **All of them are truly permanent**. [SOF ¶ 179].

In an effort to differentiate the design of the SNF from the filter implanted in Ms. Hyde, Defendant points out that [redacted] testified that the ability to be retrieved was a benefit he considered in choosing Ms. Hyde's filter. [Deft's Mtn. for Summ. J. at 10:27-11:1]. [redacted] also testified, however, that he understood [redacted] [SOF ¶ 180]. [redacted] not nullify the argument that the permanent predicate device (the SNF) was a reasonable alternative design.

The optional retrievability cannot be said to be "a *functional element*," of the G2/G2X filter as Bard asserts. [Deft's Mtn. for Summ. J. at 11 n. 6, citing *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1999)]. Wisconsin courts have made clear that a product is not a reasonable alternative design "when some ingredients cannot be eliminated from a design without eliminating the product itself." *Godoy v. E.I. du Pont de Nemours & Co*., 319 Wis.2d 91, 118 (Wis. 2009).. Plaintiffs can easily concede this law and still maintain that the SNF is a reasonable alternative design to the G2/G2X because the optional retrieval feature of the G2/G2X is not an ingredient that makes the product itself. As stated, the G2/G2X was just as much a permanent device as an optional device; in fact, it is the similarity to its permanent predecessors that accomplished its clearance by the FDA. Certainly, if the device can be both permanent and temporary, it cannot be argued that one or the other is the functional element or an ingredient that makes the product itself.

Alternatively, Plaintiffs have expert evidence to support a safer alternative design to the G2/G2X would simply be one that incorporated caudal anchors or any other feature that would prevent caudal migration. [SOF ¶¶ 168-70]. It is the filter's propensity to tilt, leading to perforation, and vice versa that constitutes the manifestation of the device's design defect. A design that included an anchoring system is a safer alternative design. *Id*. In fact, in 2006, a competitor's IVC filter, the Greenfield™ Filter had already being redesigned to include an anchoring system as a safer alternative design; after learning of a 30% instance of caudal migration with its Greenfield filter, Boston Scientific redesigned the filter by flipping 2 hooks, creating an anchoring system to prevent such migrations. [SOF ¶ 86]. This evidence undeniably supports Plaintiffs' contention that there were safer alternative designs to the G2/G2X filter and that the G2/G2X filter, as designed, was defective.

D. There Is Sufficient Evidence of Negligent Failure to Warn (Count VII)

i. The Learned Intermediary Doctrine Should Not Apply

The Wisconsin Supreme Court has not had the opportunity to address or adopt the learned intermediary rule. *See Forst v. SmithKline Beecham Corp.*, 602 F.Supp. 2d 960, 968 (E.D. Wis. 2009). Bard's argument here is based on the Wisconsin Supreme Court's "likely" adoption of the defense. However, it is not as likely as Bard purports. It is true that several courts have used the rule without mentioning that the state Supreme Court has not yet expressly adopted it. *See, e.g.*, *Menges v. Depuy Motech Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law). Just as many, if not more, cases (and cases that are more recent than those cited by Bard from 1981, 1999, and 2003) have declined to apply the learned intermediary doctrine under Wisconsin law. *See Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817, at *5 (E.D. Wis. Feb. 26, 2013) ("Wisconsin does not apply the learned intermediary doctrine…"); *Forst*, 602 F.Supp. 2d at 968 (declining to adopt the learned intermediary rule "without some indication that the state's highest court would apply the doctrine if given the opportunity to do so." (quotation marks omitted)); *Peters v. AstraZeneca, LP*, 417 F.Supp. 2d 1051, 1054 (W.D. Wis. 2006) ("this court will not create Wisconsin law without some indication that the state's highest court would apply the doctrine . . .").

Even in states, such as California, that allow for the learned intermediary doctrine, it only applies when an adequate warning has been given. *See e.g.*, *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1117 (1996). As described, *infra*, the information Bard did provide to doctors and patients lacked specificity and left out information that prevented them from being adequate warnings under Wisconsin law. As such, [redacted], Ms. Hyde's implanting physician, was not "learned" and thus the learned intermediary doctrine cannot apply. Moreover, Bard concedes that they had a duty to advise both doctors ***and*** patients of a number of significant risks, data and conditions of their filters (like Ms. Hyde's iteration of the Bard filter), but that they kept this information concealed

and excluded from their IFUs. [SOF ¶¶ 115(a-h)]; *see also* Bard's SOF ¶¶ 18-19 for G2X and Eclipse IFUs].

Bard concealed internal analysis concluding G2 products (like Ms. Hyde's) caused an unreasonable, unacceptable, and undesirable risk of serious injury and death. [SOF ¶ 115(g)]. Mr. Ganser admits that Bard should have communicated to physicians and patients that the Recovery filter—the G2's predicate device—does not have the ability to carry out its intended function of preventing pulmonary emboli, [SOF ¶ 115(h)]; that Bard was still trying to figure out why its devices were breaking and migrating, [SOF ¶¶ 115(a), (b), and (k)]; that the G2 filter was determined to have an unacceptable risk profile based on its internal risk analysis protocol [SOF ¶ 115(j)]; and that Bard should have communicated to physicians and patients that the G2/G2X filters needed to be redesigned to deal with migration, tilt, and perforation, [*id.*]. This evidence alone raises a material question of fact, thus defeating the learned intermediary doctrine as Bard admits that patients should have been advised, as well as doctors.

ii. Bard's Warnings Were Inadequate

Wisconsin courts consistently hold that the adequacy of warnings is a question of fact for the jury to decide. *See, e.g., Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1321 (7th Cir. 1983). In *Forst*, the Eastern District of Wisconsin held that regardless of whether the learned-intermediary doctrine applied, the plaintiff had raised a genuine issue of material fact as to whether there was an adequate warning and thus, summary judgment could not be granted as it had become a question for the jury to decide. *Forst*, 602 F.Supp. 2d at 968.

There have been instances where courts applying Wisconsin law have stated that "[a]lthough the adequacy of a warning often presents a factual issue for a jury, that is not always so." *Kurer v. Parke, Davis & Co.*, 272 Wis. 2d 390, ¶ 24 (2004). However, such cases reveal that plaintiffs submitted little to no evidence regarding the adequacy of the warning such that no reasonable jury could find that the defendant was negligent in their failure to warn. *See, e.g., Alvarado v. Sersch*, 262 Wis. 2d 74 (2003). Here, Plaintiffs

have presented and uncovered a vast amount of evidence revealing that Bard knew the G2/G2X was defective and dangerous, and inadequately warned patients of the defects and increased risk of complications and injuries.

Bard was aware of problems with the G2/G2X filter, including complaints that the filters were tilting, perforating, and migrating beyond their implantation site. [SOF ¶¶ 79, 81, 89, 91, 94]. As discussed above, according to Bard's own internal complaint data, the G2 was experiencing significantly higher rates of adverse events when compared to other filters. [SOF ¶¶ 79, 81-84, 89]. Bard was told by Dr. Kris Kandarpa that the G2 Family of filters was in need of redesign for patient safety and effectiveness reasons and as such, the G2X filter should not have been marketed at the time that device was implanted in Ms. Hyde's IVC. [SOF ¶¶ 91-92].

Bard knew, before conducting its EVEREST clinical study (commencing mid-2006) on retrievability, and after market clearance that (1) it had a problem with caudal migration and tilt that it didn't expect when they launched the G2; (2) that there were unexpected reports of caudal migration; and (3) recognized these were caused by design problems with the G2 that (4) needed to be fixed by redesign before they launched the EVEREST study. [SOF ¶¶ 79, 81]. The data coming in on the G2 filter in the first four to six months that it was on the market showed that it had stability problems with respect to tilt and caudal migration, and despite its brochure, the G2 did not take strength and stability to a new level compared to the Simon Nitinol and Recovery filters. [SOF ¶ 79]. Based on internal company documents in the first three to six months that the G2 was on the market, it showed stability problems that were in fact not improved over the Simon Nitinol filter. [*Id.*]. Further, internal company documents reveal that Bard was concerned there were design problems and was redesigning the G2 to improve its safety performance and mitigate risks to patients. [SOF ¶¶ 79, 81, 91, 94]. Which, according to Bard's industry standards expert, Donna Tillman, required the device to be removed from the market until fixed. [SOF ¶ 185].

With all of this knowledge, Bard distributed materials related to the G2 IVC filter that indicated that it had increased migration resistance, improved centering, and enhanced fracture resistance. [SOF ¶¶ 73-74]. Bard representatives were out in the field, representing to physicians, patients, and the public, that the G2 Filter Family had increased migration resistance, migration resistance across an even broader range of caval distension and higher pressures, and that the G2 Filter System was better technology than the Recovery and the SNF. [SOF ¶ 69].

Bard's labeling, which includes the IFU[8],that Bard has argued contained an adequate warning, failed to warn of the ***increased*** risk of adverse events when compared to the SNF and competitor filters. [SOF ¶ 72]. Instead, the G2/G2X/ IFUs included general, broad strokes language that implied the risks of various adverse events were the same as all other IVC Filters. [SOF ¶ 74]. This generalized warning is wholly inadequate when compared to the knowledge that Bard had regarding the danger posed to patients, such as Ms. Hyde, by the G2X IVC Filter.

A reasonable alternative warning would feature all the information that Bard knew regarding the G2/G2X's performance and propensity to malfunction at a higher rate than other Bard filters and competitive filters, rather than the general, inadequate warning found in the IFU. Never did Bard share its filter concerns with the medical community or patients, notwithstanding the fact that Bard was actively engaged in development of its Denali filter. [SOF ¶ 116]. Rather, Bard was aware that its G2 filter, within the first 5-6 months it was on the market, was determined to have an undesirable and unacceptable risk profile based on its internal risk analysis protocol. [SOF ¶¶ 79, 87]. Bard Peripheral Vascular President, John McDermott testified that doctors would want to know information and analysis the company possessed comparing the performance, risks and safety profile of Bard's IVCFs from Adverse Event Reports and data; and that doctors

[8] Note that in their Motion, Bard included the Eclipse IFU in their argument [Bard's Motion at Page 14]. As argued, *supra*, the filter Ms. Hyde received was a G2X. Nonetheless, as Bard points out, the warnings at issue in the IFU were the same in the G2, G2X, and Eclipse IFU [See Bard's Statement of Fact ¶¶ 18-19].

would want to know the information Bard had about other doctor's experiences with their IVCFs; that this data and information was important to doctors' decision-making. [SOF ¶¶ 121-25].

Finally, while Bard's motion argues that Plaintiffs have failed to present a reasonable alternative warning, Mr. Ganser and one of Bard's experts, Donna Tillman, have admitted that design defects cannot be corrected with just a warning; defects must be corrected by fixing and correcting the design features. [SOF ¶ 185].

E. Negligent and Fraudulent Misrepresentation/Concealment Claims (Counts VII, XII, XIII) and Claim for Violation of Wisconsin Law (Count XIV)

Plaintiffs agree that their claims for Negligent and Fraudulent Misrepresentation and Concealment and Violation of Wisconsin Law all have reliance elements. However, Plaintiffs have and can present evidence that raises a genuine issue of material fact as to both [redacted] reliance (and thus, Ms. Hyde's) on Bard's misrepresentations and omissions to the FDA.

At his deposition, [redacted] testified that he trusts the FDA more than medical device companies and that he is comfortable using any filter that is FDA approved (which the G2 family of filters was not).[9] [SOF ¶ 181]. [redacted] also testified that in 2011, it was his understanding that all FDA-cleared IVC filters had the same performance and comparable risks of complications, such as migrations and fractures. [SOF ¶ 182]. However, given the various misrepresentations and omissions Bard presented to the FDA to get the G2 filter cleared as a permanent and then retrievable device, [redacted] reliance on the FDA was essentially reliance on Bard's fraudulent misrepresentations and concealment. As discussed above, Bard had knowledge that the G2/G2X filter performed significantly worse than other filters. [SOF ¶¶ 79, 81, 89, 91, 94].

[9] Pending before the Court is Plaintiff's request to redepose [redacted] with such evidence he was precluded from testifying to because of the instructions by [redacted] personal attorney.

Bard downplayed the nature, extent and purpose of the G2 design changes to get the G2 cleared faster and rushed to market as "substantially equivalent" to the Recovery. [SOF ¶¶ 311, 314]. Significantly, in Bard's Traditional 510(k) for the G2 cleared on August 29, 2005, Bard refers to the design changes as "primarily dimensional;" and further misrepresents that there are "no material changes" to the Recovery predicate device. [SOF ¶¶ 312-313]. Nor did Bard give any indication that these were major design changes intended to reduce migration, fracture and tilt so prevalent in the Recovery. [SOF ¶ 314].

This also enabled Bard to avoid admitting to FDA that these were necessary design changes due to significant life-threatening complications reported with the predicate Recovery, which Bard left on market shelves and which remained implanted in patients without adequate warning of the risks. At this time, Bard was aware of problems with the G2 filters, including complaints that the filters were tilting, perforating, and migrating. [SOF ¶¶ 62, 77-79].

Bard also knew that tilting by a filter could place a patient at an increased risk of adverse events and impair the filter's ability to prevent pulmonary embolism. [SOF ¶ 115(b)]. Bard withheld this information from the FDA. [SOF ¶¶ 19, 26, 88].

Bard's fraud can be traced as far back as the Recovery Filter, which was the predicate device to Ms. Hyde's G2X filter, and which was supposed to be "substantially equivalent" to the G2 Filter Family. Bard withheld pertinent safety data from the FDA regarding migration resistance. [SOF ¶¶ 19, 26, 88, 313-314].

At her deposition, Kay Fuller, the Bard Regulatory Affairs specifically handling the Recovery 510(k) application expressed her concerns regarding the truthfulness and accuracy of what Bard was submitting to the FDA. [SOF ¶ 187]. As Ms. Fuller testified, a Truthfulness and Accuracy Statement must be signed when she would submit a 510(k) application to the FDA. This document says that to the best of the signatory's knowledge, the information in the 510(k) is truthful, accurate, and does not contain any material information omitted. [SOF ¶ 186]. For the Recovery 510(k) application, Ms. Fuller did

not sign the Truthfulness and Accuracy statement because she was concerned that Bard would not be able to address the FDA's questions and she did not believe that the company understood the failure modes, specifically fatigue resistance, to the level that they were representing to the FDA. [SOF ¶ 187]. Additionally, Ms. Fuller did not sign because she did not feel like Bard had adequately addressed the fracture failure mode and had not taken adequate corrective actions. [SOF ¶ 188]. This was the first time in Ms. Fuller's career that she was not comfortable signing the Truthfulness and Accuracy statement in an application to the FDA. [SOF ¶ 189]. Since Ms. Fuller would not sign the Truthfulness and Accuracy statement, Carol Vierling, without permission, signed Ms. Fuller's name on the 510(k) submission. [SOF ¶ 190].

As such, even though [redacted] relied on the FDA and not Bard, in relying on the FDA and assuming that all filters had similar compilation rates, [redacted] was relying on the untruthful and misleading ways Bard got its products cleared by the FDA's 510(k) process.

Additionally, in his deposition, [redacted] states that he reviewed the G2/G2X IFU. [SOF ¶ 183]. As discussed above, the IFU for the G2 Filter family failed to warn of the increased risk of adverse events, such as migration or movement of the filter, with those filters versus the SNF and competitor filters – despite Bard knowing this was important information for a physician to be aware of. [SOF ¶ 72]. The IFUs include language implying that the risk of various adverse events associated with the Recovery and G2 Filter Family are the same as all other IVC filters. [SOF ¶ 74]. Those IFUs state that migration and movement are "known complications of vena cava filters." [*Id.*]. This is the same language Bard conveyed to physicians in its "Dear Doctor" and "Dear Colleague" letters. There is nothing about that language that advises physicians or patients of the increased risk of those adverse events or the admitted design deficiencies with the Recovery/G2 Filter Family versus the SNF or competitor IVC filters – it simply provided a general, blanket statement, dating back decades and including filters since

redesigned or no longer sold, about IVC filters, and it is void of any pertinent safety information specific to Bard's dangerous filters. [*Id.*].

Bard's former corporate executive, Mr. Ganser, provided testimony regarding all of the various things that Bard should have communicated to physicians and patients, either through the IFU or other forms of communication. [SOF ¶¶ 115(a-j)]. Of course, both [redacted] and Ms. Hyde relied on Bard to not conceal exactly what Mr. Ganser testified should have been revealed to both of them, and Bard not doing so did not allow both to engage in a complete, educated and informed consent process prior to the implantation of the G2X device on [redacted]. [SOF ¶ 150].

In relying on the FDA and the G2/G2X IFU, [redacted] was relying on Bard's countless untruthful and negligent misrepresentations and omissions. As such, Plaintiffs have presented ample factual evidence to pass the standard for summary judgment on these causes of action.

Bard also argues that the fraud-based causes of action fail under Wisconsin Statute 100.18 because Plaintiffs have not alleged or shown evidence of pecuniary loss. Plaintiffs do not read the statute as requiring proof of pecuniary loss. Bard cites generally to the 12-part statute, but Plaintiffs assume they are referring to 100.18(11)(b), which in no way ***requires*** Plaintiffs to prove pecuniary loss. Section (11)(b) merely sets forth instructions ***if*** a person has suffered pecuniary loss. It does not require it to prove a claim for fraudulent misrepresentation. Various case law examples indicate that the elements of fraudulent misrepresentation are: (1) that the statement was false; (2) that the statement was made with the intent to defraud and for the purpose of inducing another to act upon it; and (3) reliance and action upon that representation, causing ***injury or damage***. *See, e.g., Green Spring Farms v. Kersten*, 136 Wis. 2d 304, n. 5 (Wis. 1987) (emphasis added). Moreover, Plaintiffs have, in fact, suffered pecuniary loss as they had to pay for Ms. Hyde's [redacted] [SOF ¶ 35].

IV. CONCLUSION

In conclusion, under Wisconsin's choice-of-law rules, Nevada substantive law should apply to the *Hyde* case as it is the location of injury and current domicile of the Plaintiffs.

With regard to Plaintiffs' Strict Liability – Failure-to-Warn Claim (Count II), Plaintiffs have shown that the rebuttable presumption (the "government rules defense") should not apply as the G2/G2X were cleared via the FDA's 510(k) process, which has no bearing on a products safety or efficacy. Moreover, even if the presumption were to apply, Plaintiffs have presented enough evidence to rebut that presumption, as Bard's products were defective and failed to give an adequate warning to doctors or the public. Count II is not precluded under Wisconsin's bar of strict liability claims for damages caused by known, inherent characteristics of the product as the G2/G2X filters caused adverse events at rates well beyond competitive filters. A reasonable alternative warning would have included information sufficient for doctors and patients to make a fully informed decision on which filter to use, given the information that Bard concealed.

Bard's Motion for Summary Judgment as to Plaintiffs' Strict Liability – Design Defect (Count III) should also not be granted, as Plaintiffs have presented numerous genuine issues of material fact showing that Bard's G2 and G2X filters were defectively designed. A reasonable alternative design existed in the Simon Nitinol Filter, which experienced next to no adverse events in its long history on the market. Additionally, Plaintiffs have expert testimony that shows a safer alternative design would have been a filter with caudal anchors, such as the Greenfield™ Filter. Wisconsin's bar on strict liability claims for damages caused by known, inherent characteristics of the products and government rules defense do not apply to Plaintiffs' Strict Liability - Design Defect claim for the same reason they do not apply to the Strict Liability - Failure-to-Warn claim, as stated above.

Plaintiffs' Negligent Failure-to-Warn claims should also survive summary judgment. As argued, there are multiple instances of testimony from Bard's own

witnesses and experts that point out how inadequate Bard's warnings were. The inadequacy of Bard's class warning featured in the G2/G2X IFU defeat any attempted use of the learned-intermediary doctrine, which consequently, has not even been officially adopted in Wisconsin.

Finally, Plaintiffs' various misrepresentation and concealment claims (Counts VIII, XII, XIII, and XIV) should not be dismissed as Plaintiffs have shown evidence that [redacted] relied on the FDA from which Bard concealed information during the 510(k) approval process and relied on the G2/G2X IFU, which again, featured an inadequate and misleading warning regarding the safety of Bard's filters. Moreover, [redacted] and Ms. Hyde relied on Bard to not conceal the long list of facts and information that Mr. Ganser admitted Bard concealed and should have warned doctors **and** patients about.

As such, Bard's Motion for Summary Judgment should be denied in its entirety.

RESPECTFULLY SUBMITTED this 29th day of October, 2017.

GALLAGHER & KENNEDY, P.A.

By: */s/* Mark S. O'Connor
Mark S. O'Connor (AZ Bar No. 011029)
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs